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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,418	09/29/2000	David M Spencer	P01934 US1	8517

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EXAMINER

ZEMAN, ROBERT

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 03/22/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/647,418

Applicant(s)

SPENCER ET AL.

Examiner

Robert A Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 5-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other:

DETAILED ACTION

Applicant's election of Group I, without traverse, in Paper No. 4 is acknowledged.

Claims 5-27 have been withdrawn from consideration. Claims 1-4 are currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the use of the term "chemical inducer-binding domain". It is unclear what is meant by said term. Is the binding domain a structural part of the chemical inducer or does said domain bind to the chemical inducer? Additionally, it is also unclear what "a chemical inducer" means. What is being induced? Is the "chemical" the causative agent or what is being "induced"? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 2 is rendered vague and indefinite by the use of the term "adaptor" molecule. It is unclear what is meant by said term. What type of "adaptor" molecule is Applicant referring to? How does it function? Additionally, the specification is silent on what constitutes an "adaptor" molecule, though it does describe "adapter" molecules (see page 19). As written, it is impossible to determine the metes and bounds of the claimed invention.

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Claims 2-4 are rendered vague and indefinite by the use of the phrase “said apoptosis signal inducing factor is...” The antecedent claim recites that the inducing factor “is a signal transducing factor”. The rejected claims recited alternatives for what the “inducing factor” can be. However, since all depended claims have all the limitations of their antecedent claims, the “inducing factor” is already defined as “a signal transducing factor”.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

This instant claims are drawn to a conditionally (i.e. only lethal in the presence of the chemical inducer) lethal molecule comprising a chemical binding domain and an apoptosis

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inducing factor wherein said apoptosis inducing factor is an apoptosis signal transducing factor (claim 1) an adaptor molecule or a protease (caspase).

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Crabtree et al. (U.S. Patent 5,834,266).

Crabtree et al. disclose inducible Fas chimeras that are induced by activating an artificial receptor that is the product of a constitutively expressed “responder” gene (see Examples 4b and 4c). Since said chimeras comprise a “chemical binding domain” and a apoptosis inducing factor (Fas), Crabtree et al. anticipates all the limitations of the rejected claim.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Crabtree et al. (WO 95/02684 --IDS-5).

Crabtree et al. disclose inducible Fas chimeras that are induced by activating an artificial receptor that is the product of a constitutively expressed “responder” gene (see Examples 4b and 4c). Since said chimeras comprise a “chemical binding domain” and a apoptosis inducing factor (Fas), Crabtree et al. anticipates all the limitations of the rejected claim.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Reeves (WO 97/20463 --IDS-5).

Reeves discloses a drug regulated retroviral vectors, which comprise a drug binding domain and an apoptosis inducing factor. Reeves further discloses that said vectors can comprise “programmed cell death gene(s)” (see page 23) and more specifically the ICE protease (see Example 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

This instant claims are drawn to a conditionally lethal molecule comprising a chemical binding domain and an apoptosis inducing factor wherein said apoptosis inducing factor is an apoptosis signal transducing factor (claim 1) an adaptor molecule or a protease (caspase).

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reeves (WO 97/20463 --IDS-5) in view of Yuan (Current Opinion in Cell Biology, Vol. 9, pages 247-251 --IDS-5).

Reeves discloses drug regulated retroviral vectors, which comprise a drug binding domain and an apoptosis inducing factor. Reeves further discloses that said vectors can comprise

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“programmed cell death gene(s)” (see page 23) and more specifically the ICE protease (see Example 2). Reeves differs from the instant invention, as recited in claims 2-4) in that it does not specifically recite the use of a caspase or an adaptor molecule as the “apoptosis-inducing factor”. Yuan et al. discloses the apoptotic pathways induced by TNF-R1 and CD95 (Fas). Consequently, it would have been obvious for one of skill in the art to use the various molecules disclosed by Yuan in order to exercise finite control over the induction of apoptosis. One would have had a high expectation of success since Reeves discloses that programmed cell death genes can be used in his drug regulated vectors and Yuan describes the role/effect each of the components of the disclosed apoptotic pathway has in said pathway.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crabtree et al. (US Patent 5,834,266 in view of Yuan (Current Opinion in Cell Biology, Vol. 9, pages 247-251 -IDS-5).

Crabtree et al. disclose inducible Fas chimeras that are induced by activating an artificial receptor that is the product of a constitutively expressed “responder” gene (see Examples 4b and 4c). Crabtree et al. differ from the instant invention in that it does not specifically recite the use of a protease, such as caspase, or an adaptor molecule as the “apoptosis-inducing factor”. Yuan et al. discloses the apoptotic pathways induced by TNF-R1 and CD95 (Fas). Consequently, it would have been obvious for one of skill in the art to use the various molecules disclosed by Yuan in order to exercise finite control over the induction of apoptosis. One would have had a high expectation of success since Reeves discloses that program cell death genes can be used in

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his drug regulated vectors and Yuan describes the role/effect each of the components of the disclosed apoptotic pathway has in said pathway.

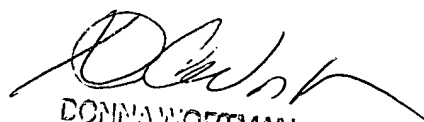
Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donna Wortman can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
March 21, 2002